PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
RLL-320WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB 03/06007	16.12.2003	16.12.2002

International Patent Classification (IPC) or both national classification and IPC

A61K9/52

Applicant

RANBAXY LABORATORIES LIMITED et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15.07.2004	17.01.2005

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/06007

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-10 as originally filed

Claims, Numbers

1-48 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 45-48

because:

☒ the said international application, or the said claims Nos. 45-48 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	27-44
	No:	Claims	1-26, 45-48
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-48
Industrial applicability (IA)	Yes:	Claims	1-44
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Section III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 45-48 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Section V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

   D1: US 2001/043945 A1
   D2: EP-A-0 439 858
   D3: EP-A-0 250 038
   D4: WO 92/15285 A

   If not indicated otherwise, the relevant passages are those mentioned in the International Search Report.

   D1 discloses (see e.g. examples) an extended release composition comprising a blend of phenytoin sodium and hydrophilic polymers (hydroxyethyl cellulose and/or hydroxypropyl methylcellulose).

   D2 discloses an extended release composition comprising a blend of phenytoin sodium and hydrophilic polymers such as carboxymethyl cellulose or hydroxypropyl methylcellulose.

   D3 discloses an extended release capsule comprising a blend of an active ingredient (e.g. phenytoin) and hydrophilic polymers (polyvinylpyrrolidone and carboxy vinyl

polymer).

D4 discloses an extended release composition (e.g. capsules) comprising an active ingredient and hydrophilic polymer (starch). Example 29 discloses a blend of phenytoin sodium and starch.

2. It is clear from the description on page 5, lines 1-17 that it is essential to the definition of the invention that the blend comprises "a powder which is filled into capsules". Since independent claims 1 and 45 do not contain this feature they do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

3. The subject-matter of independent claims 1 and 45 is not novel (Art. 33(2) PCT) over D1-D2 and D4, each document taken separately (see above under item 1).

It is here pointed out that the desideratum "wherein the blend forms a matrix after contacting an aqueous media and the matrix retains at least about 20% of the phenytoin after 1 hour" does not appear to represent any distinguishing feature with respect to the cited prior art documents.

4. The subject-matter of independent claim 27 is novel (Art. 33(2) PCT) since it has not been disclosed in its entirety in the available prior art documents.

5. The subject-matter of claim 27 only differs from D1 (see above under item 1) in specifying that the blend is screened. It differs from D3 (see above under item 1) only in specifying that the phenytoin is used as the sodium-salt.

However, these slight constructional changes are considered to come within the scope of customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Furthermore, it is here pointed

out that it is well known to use hydrophilic polymers as extended release carriers (see e.g. D4, p. 4, first paragraph).

Consequently, the subject-matter of independent claim 27 lacks an inventive step (Art. 33(3) PCT) over D1 and/or D3.

5. Having regard to the disclosures of D1-D4, dependent claims 2-26, 28-44 and 46-48 do not appear to contain new and/or inventive features and are only allowable when related to an independent claim which fulfils the requirements of the PCT.

6. For the assessment of the present claims 45-48 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.